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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,933	02/10/2004	Michael D. Kluetz	CGL03/0339US01	3155

7590 02/05/2007
Edward Levine, Esq.
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EXAMINER

CHUI, MEI PING

ART UNIT	PAPER NUMBER
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1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/775,933

Applicant(s)

KLUETZ ET AL.

Examiner

Helen Mei-Ping Chui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/14/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, 70-71 drawn to a composition for particulate plant sterols having defined particle size distribution, classified in class 424, subclass 455 and 489, for example.
- II. Claims 21-44, 58 drawn to a method for making a particulate plant sterol composition comprising steps of cooling followed by impact milling or attrition milling a cooled plant sterol starting material.
- III. Claims 45-57, 59 drawn to a method for making a particulate plant sterol composition comprising milling a plant sterol starting material by compressed air.
- IV. Claims 60-69, 72-83 drawn to a method for making a dispersed particulate plant sterol composition comprising mixing or homogenizing a said particulate plant sterol composition (for example: pulp) with an aqueous material.

The inventions are distinct, each from other because of the following reasons:

Inventions I and II-IV are directed to patentably distinct product and methods of making said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant

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case, the method as claimed in inventions III to VI can be practiced to make another materially different product or product can be made by materially different process as evidenced by instant claims (see invention II-IV).

Inventions III and IV are directed to patentably distinct processes of making a particulate plant sterol composition. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, while the inventions as claimed are both practiced by milling processes, but the inventions as claimed have a different manufacturing design (i.e., cooling a plant sterol starting material followed by milling the cooled plant sterol starting material verses directly milling the plant sterol starting material). The inventions as claimed also have a distinct process outcome (i.e., smaller particle size and spherical particle shape result from attrition milling process verses larger particle size result from mechanical impact milling process).

Inventions II and III (or IV) are directed to patentably distinct processes of making a particulate plant sterols composition. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). As evidence by instant claims, while inventions II-III are utilizing milling a said plant sterol composition, whereas inventions IV is made by

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mixing or homogenizing a said plant sterol composition. Therefore, in the instant case, inventions as claimed have a different manufacturing design (i.e., mixing verses homogenizing) and a different materially design (i.e., fine particle verses liquid form of plant sterol composition).

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden (see MPEP § 808.02). As a result, restriction for examination purposes as indicated is proper.

Election of Species

This application contains a plurality of disclosed patentably distinct species as follow: (a) Gap mill or vortex mill, etc. (see claims 33 or 45). (b) Forms of composition (i.e., dispersion, power, aqueous composition, see claims 15-18). The disclosed species are patentably distinct, each from the other, as they have different operation mechanism and/or physical properties. Therefore, election of species requirement is proper because of the above reason of undue search burden.

Even though this requirement is traversed, applicant is required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of said milling process from invention III for prosecution on the merits to which the claim(s) shall be restricted if no generic claim is finally held allowable. Currently, claim 21 is generic.

Rejoinder Practice

The examiner has required restriction between product (Inventions I or II) and method of making (Inventions III-VI) claims. Where applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn method of making that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Method of making that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement of restriction between the product claims and the rejoined method of making claims will be withdrawn and the rejoined method of making claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and method of making claims may be maintained. Withdrawn method of making claims that are not commensurate in scope with an allowable product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant are advised that the method of making claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise

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include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Where Applicant elects claims directed to method of making (Invention III-VI), applicant is required under 35 U.S.C. § 121 to elect a single disclosed milling process (if invention III is elected, then applicant is required to elect either impact milling or attrition milling from claim 21, for example) to be considered with the elected method of making claims for examination. Applicant is advised that a fully responsive reply to this requirement must include an explicit identification of the elected milling process that is elected consonant with this requirement, and a listing of all claims readable including any claims subsequently added thereto, which are readable upon the elected species. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, applicant must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments

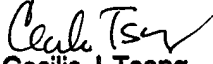
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submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang or Cecilia Tsang can be reached on 571-272-0811 and 571-272-0562, respectively. The fax phone number for the organization where the application or proceeding is assigned is 571-273-9078.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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